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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,432	12/12/2003	Eric Thwaites	10281.400-US	3883
25907	7590	11/16/2006	EXAMINER	
NOVOZYMES, INC. 1445 DREW AVE DAVIS, CA 95616			PETERSEN, CLARK D	
			ART UNIT	PAPER NUMBER
			1657	

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/734,432	Applicant(s) THWAITES, ERIC	
	Examiner Clark D. Petersen	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 12-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-8 and 12-15 in the reply filed on 1 August 2006 is acknowledged.

Claim 16 was additionally examined because examiner's search revealed art relevant to claim 16.

Claims 9-11 and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1 August 2006.

Claims 1-8 and 12-16 were examined are pending in the instant application.

Claims 1-8 and 12-16 were examined on their merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

Art Unit: 1657

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/463939. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim the same invention. Claims 1-8 of Application No. 10/463939 were amended in the applicant's amendment filed 22 May 2006, in which claims 9-16 were cancelled, and claim 1 was amended from reciting "a glycosaminoglucan of interest" to "a glycosaminoglycan". Therefore, claim 1 as

Art Unit: 1657

amended 22 May 2006 is broader in scope than claim 1 originally filed 18 June 2003. Instant application No. 10/734432 contains the exact language as claim 1 of application no. 10/463939 as originally filed 18 June 2003; however, because claim 1 of 10/463939 has been amended, instant claim 1 and current claim 1 of 10/463939 do not contain exactly the same language. However claim 1 of the instant application is obvious in comparison with currently amended claim 1 of application no. 10/463939. Additionally, claims 2, 3, 4, 6, 7, and 8, which depend from instant claim 1, share exactly the same language as claims 2, 3, 4, 6, 7, and 8 which depend from claim 1 of application no. 10/463939, and therefore are also rendered obvious. Claim 5 of the instant application, which recites a glycosaminoglycan molecular weight of 700 to 15,000,000 Daltons, overlaps with the range of 10,000 to 15,000,000 Daltons recited in claim 5 of application no. 10/463939, and therefore is also obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-6, 8 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Bracke et al (US Patent #4,517,295, issued 14 May, 1985). Bracke et al

Art Unit: 1657

teach a method of purifying hyaluronic acid from bacterial culture. As part of the process of producing hyaluronic acid, the bacteria are grown in a fermentation broth comprising the divalent salts calcium chloride and magnesium sulfate, reading on the limitation that the method of instant claim 1 comprises adding a divalent salt to the the fermentation broth, as well as instant claim 6, which limits that divalent salt to magnesium or calcium (see col. 2, lines 45-65, for example). The method taught by Bracke et al comprises growing *streptococcus* bacteria in a fermentation broth. This *streptococcus* species naturally produces hyaluronic acid and secretes it into its growth medium (see col 2, lines 5-34, for example). The cells are then flocculated and separated from the fermentation broth which contains the desired hyaluronic acid (see col. 3, lines 32-45, for example). Specifically, *streptococcus* is a prokaryote, reading on claim 2. The hyaluronic acid produced by this method has a molecular weight of 55,000 (see col. 1, lines 48-60, for example). Once flocculated, the bacteria are removed by a filtration process (see col 3, lines 46-51, for example). Flocculation of the *streptococci* is achieved in part by addition of trichloroacetic acid, reading on the limitation of instant claim 16 that one more flocculating agent is added to the fermentation broth (see col. 3, lines 32-45, for example). Therefore the teachings of Bracke et al are deemed to anticipate the instant claims 1, 2, 4-6, 8, and 16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weigel et al (International Patent Publication #WO99/23227, published 14 May, 1999) in view of Kanani et al (US Patent #3,878,093, issued 15 Apr 1975).

Weigel et al teach a method of fermenting a microorganism. This microorganism is capable of producing a glycosaminoglycan and secreting it into its medium. In particular it is advantageous, after the glycosaminoglycan has been produced, to sequester the microorganism from its fermentation broth, by a method of flocculating the microorganism (see p. 63, lines 6-23, for example). In particular the microorganism that produces the glycosaminoglycan can be either a eukaryote or a prokaryote (see p. 58, line 27 to p. 59, line 8, for example; see p. 59, line 18 to p. 60, line 8, for example). In particular, the use of *Bacillus subtilis* is a preferred embodiment of a cultured organism for producing the glycosaminoglycan hyaluronic acid (see p. 59, lines 9-17, for example). These hyaluronic acid molecules span a range of sizes, but fall within the range recited in the instant claim 5 (see p. 79, lines 11-23, for example; see Fig. 9, for example).

Weigel et al do not expressly teach addition of a divalent salt as a flocculating agent.

Weigel et al do not expressly teach adjusting the fermentation broth pH.

Weigel et al do not expressly teach heating the fermentation broth to between 30 and 60 degrees C.

Kanani et al teach that it is possible to separate a microorganism from its fermentation broth by flocculation. This flocculation can be achieved by raising the pH of the fermentation broth to 8 to 11, followed by heating the fermentation broth to a minimum of 50 degrees Celsius; and changing the pH of the fermentation broth to between 2 and 5 by addition of acid (see col. 1, lines 36-48, for example). In particular, flocculation can be achieved by addition of calcium hydroxide (see col. 2, lines 33-47, for example). The adjustment of particular conventional working conditions (e.g., the the concentration of divalent salt recited in the instant claim 7) is deemed a matter of judicious selection and routine optimization of a result-effective parameter, which is well within the purview of the skilled artisan. Regarding temperature, the broth can be allowed to cool before addition of acid as the final step of flocculation; this temperature can be in the range of 20 to 50 degrees Celsius. In particular, Kanani et al note that their method is well-suited to separating the genus *Bacillus* from its fermentation broth (see col. 1, lines 48-62, for example). Kanani et al note that their method produces large, strong flocs that have a good rate of settling. Their method enables the size of settling tanks and number of centrifuges that are used for separating bacterial flocs in some cases to be reduced (see col. 3, lines 32-50, for example).

A person of ordinary skill in the art at the time the invention was made would have been motivated to add divalent salt, change the pH of the fermentation broth, and heat the fermentation broth, because Weigel et al teach that *Bacillus* can be induced to secrete hyaluronic acid into their fermentation broth, and that it is desirable to separate the bacteria from their fermentation broth, and Kanani et al teach a method of producing strong, easily separated flocs by changing pH and temperature of the fermentation broth that allows for the easy purification of hyaluronic acid demanded by Weigel et al.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to employ the flocculation method of Kanani et al in a method of producing and purifying hyaluronic acid taught by Weigel et al.

Conclusion

No claims are allowed.

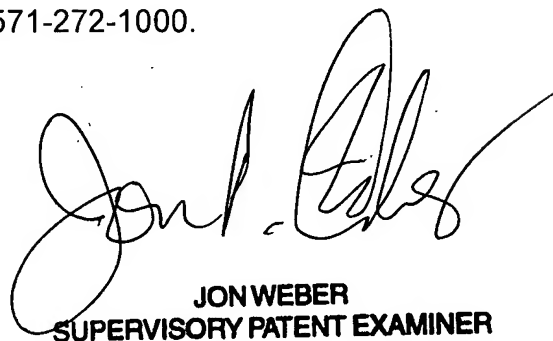
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clark D. Petersen whose telephone number is (571)272-5358. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571)272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1657

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CDP
11/10/2006



JON WEBER
SUPERVISORY PATENT EXAMINER